



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-4206]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee Small Business Qualification and Certification

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review--Open for Public Comments” or by using the search function. All comments should be identified with the OMB control number 0910-0508. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-45, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device User Fee Small Business Qualification and Certification

This information collection helps support implementation of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107-250) and FDA’s Medical Device User Fee program. Current authorization for medical device user fees will be in place from October 1, 2017, until September 30, 2022.

Section 738(d)(2)(A) and (e)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(d)(2)(A) and (e)(2)(A)) define a “small business” as an entity that reported \$100 million or less of gross receipts or sales in its most recent Federal income tax return, including such returns of its affiliates, partners, and parent firms. If a firm’s gross receipts or sales are no more than \$30 million (including all affiliates, partners, and parent firms), they will also qualify for a waiver of the fee for their first (ever) premarket application, product development protocol, biological licensing application, or premarket report. A “small business” is eligible for reduced or waived fees. If an applicant does not provide information to FDA demonstrating to FDA’s satisfaction that the applicant is a small business, the applicant must pay the standard (full) fee for any application it submits.

Forms FDA 3602 (“MDUFA Small Business Certification Request for a Business Headquartered in the United States”) and 3602A (“MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States”) are submitted to FDA to demonstrate that an applicant qualifies as a MDUFA small business. The guidance “Medical Device User Fee Small Business Qualification and Certification; Guidance for Industry, Food and Drug Administration Staff and Foreign Governments”¹ describes the process by which a business may request certification as a small business and the criteria FDA will use to decide whether an entity qualifies as a MDUFA small business and is eligible for a reduction in user fees.

¹The guidance “Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments” is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-certification>.

In the *Federal Register* of December 23, 2021 (86 FR 72983), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received, however it did not respond to the functional elements solicited in our 60-day notice or suggest a revision to our burden estimate.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
FDA 3602--MDUFA Small Business Certification Request For a Business Headquartered in the United States	2,500	1	2,500	1	2,500
FDA 3602A--MDUFA Foreign Small Business Certification Request For a Business Headquartered Outside the United States	2,000	1	2,000	1	2,000
Total					4,500

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden is based on the number of applications received in the last few years and includes the time we assume necessary to prepare and submit required information. Based on our experience with Forms FDA 3602 and 3602A, we assume it will take respondents 1 hour to complete either form. We have adjusted our estimated “No. of Respondents” to better reflect recent submission volume. This adjustment results in a 2,500-hour decrease to the information collection.

Dated: April 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.